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### **Formalities**

The Examiner notes that "Exhibit A" referred to in the Preliminary Amendment filed on August 22, 2000 has not been considered. The Examiner advises that she will consider "Exhibit A" if a copy thereof is filed along with a response to the pending Office Action.

In response, and further to the Examiner's recommendation, applicants submit herewith as **Exhibit B** a copy of the "Exhibit A" referred to in the Preliminary Amendment, and respectfully request that this exhibit be considered in the subject application.

The Examiner notes that the Declaration filed on August 22, 2000 is defective and requests that a newly executed Declaration be filed in connection with the subject application. In response, applicants will file a newly executed Declaration in due course.

The Draftsperson objected to the drawings under 37 C.F.R. \$1.84 or \$1.152 with respect to certain formalities. In response, applicants annex corrected drawings hereto as **Exhibit C**.

# Obviousness-Type Double Patenting Rejection

The Examiner rejected claims 65-77 as allegedly unpatentable over claims 1-10 of U.S. Patent No. 6,106,827 ("'827 patent") under the judicially created doctrine of obviousness-type double patenting. The Examiner stated that although the conflicting claims are not identical, they are not patentably distinct from each other because claims 65-74, 76 and 77 are broader than claims 1-10 of the '827 patent, and therefore

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encompass the patented invention. The Examiner further asserts that claim 75 is obvious over claim 1 of the '827 patent.

In response to the Examiner's rejection, applicants will file a terminal disclaimer in the application at such time as the instant claims are deemed allowable.

# Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 77-79 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention.

In response to the Examiner's rejection, but without conceding the correctness thereof, applicants point out that claims 77-79 have been canceled. Thus, the rejection thereof is now moot.

#### Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 65-79 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In response to the rejection of claims 65-75, applicants respectfully traverse.

Claim 65 provides an astrocyte cell stably transfected with two DNAs comprising (i) a gene encoding a selectable marker and (ii) a gene encoding a biologically active molecule.

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Claims 66-75 depend from claim 65 and provide certain embodiments of the DNAs recited in claim 65.

In support of their traversal, applicants point out that claim 65 has been amended to clarify the antecedent basis of the promoters and DNAs recited in the claim. In view of this amendment, applicants maintain that claim 65, and likewise its dependent claims 66-75, satisfy the requirements of 35 U.S.C. \$112, second paragraph, and respectfully request that the Examiner withdraw her rejection thereof.

In response to the rejection of claims 76-79, applicants point out that these claims have been canceled, rendering the rejection moot. However, with respect to the alleged indefiniteness of claim 76, applicants request that the following remarks be made of record.

Applicants understand the Examiner's rejection of claim 76 to be based upon her belief that a "constitutive" promoter, by definition, can not also be regulatable. Applicants disagree with the Examiner's position and point out that the art teaches that all promoters have some level of transcriptional activity that is constitutive, often referred to as "basal" activity.

Specifically, regulatable promoters may be either induced or suppressed by experimentally controllable means and are understood to have either a low level of constitutive activity in the absence of an inducer or a high level of constitutive activity in the absence of a suppressor, respectively. For example, at pages 21-24 of the specification and in Figures 8-12, this application teaches a regulatable ppEnk promoter that exhibits a low level of constitutive activity in the absence of an inducer such as dopamine (Fig. 8) or apomorphine (Fig. 9).

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In view of the above remarks, applicants maintain that claims 65-75 satisfy the requirements of 35 U.S.C. §112, second paragraph.

## Summary

In view of the amendments and remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents, Washington D.C. 20231

Alan Morrison Reg. No. 37,399

ison Date

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